

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

On January 14, 2004, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Konstantyn Sz wajkun, M.D., F.A.C.C. Based on an echocardiogram dated April 22, 2003, Dr. Sz wajkun attested in Part II of Ms. Moon's Green Form that she suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 50%

3. (...continued)

presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

to 60%.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level II Benefits in the amount of \$560,748.⁵

In the report of claimant's echocardiogram, the reviewing cardiologist, Bard R. Madsen, M.D., stated that Ms. Moon had an ejection fraction of 59%. An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See Settlement Agreement § IV.B.2.c.(2)(b)iv).

In January, 2007, the Trust forwarded the claim for review by Alan J. Bier, M.D., one of its auditing cardiologists. In audit, Dr. Bier concluded that there was no reasonable medical basis for the attesting physician's finding of a reduced ejection fraction in the range of 50% to 60%. In support of this conclusion, Dr. Bier stated, "The left ventricle is vigorous and symmetrical in all projections. Clearly an ejection fraction of over 60%." Specifically, Dr. Bier observed that claimant's ejection fraction was "65%-75%."

4. Dr. Szwajkun also attested that claimant suffered from moderate aortic regurgitation. This condition is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of moderate mitral regurgitation, the only issue is claimant's ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim.

Based on the auditing cardiologist's finding that claimant did not have a reduced ejection fraction, the Trust issued a post-audit determination denying Ms. Moon's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In support of her claim, Ms. Moon submitted a letter from Dr. Szwajkun in which he stated that he measured Ms. Moon's ejection fraction using the method of discs, "the most accurate assessment of [left ventricular] size and function by echocardiography," and determined "[the] ejection fraction was 58.7." Dr. Szwajkun also stated that he was surprised by the auditing cardiologist's "reliance on a qualitative measure of [left ventricular] function over a well established quantitative assessment of volume and function." In addition, Ms. Moon asserted that there was no reason for Dr. Bier's findings to take precedence over the findings of her two cardiologists, Dr. Szwajkun and Dr. Madsen.

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Bier submitted a declaration in which he again concluded that there

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Moon's claim.

was no reasonable medical basis for the attesting physician's finding that Ms. Moon suffered from a reduced ejection fraction. Specifically, Dr. Bier stated:

I still find that the ejection fraction is over 60%, subjectively. The tracing recorded on the tape for end diastole is about 1-2 frames after true end-diastole as judged by the ECG tracing. I have calculated the ejection fraction on our equipment using the same technique and came up with an ejection fraction of 63%. Accordingly, I affirm my findings at audit, that there is no reasonable medical basis for finding of an ejection fraction of 50-60%.

The Trust then issued a final post-audit determination, again denying Ms. Moon's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Moon's claim should be paid. On January 31, 2008, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7658 (Jan. 31, 2008).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on May 30, 2008, and claimant submitted a sur-reply on December 5, 2008. Under the

Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁷ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had a reduced ejection fraction. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust

7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

to pay the claim in accordance with the Settlement Agreement.
See id. Rule 38(b).

In support of her claim, Ms. Moon reasserts the arguments made in contest, namely, that there is a reasonable medical basis for the attesting physician's finding of a reduced ejection fraction. Claimant also argued that the auditing cardiologist's conclusions were subjective and unsupported because he provided no measurements to support his findings. Claimant further contends that Dr. Bier's responses violate the Audit Rules.⁸

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Moon had a reduced ejection fraction. Specifically, Dr. Vigilante stated:

The left ventricle was normal in size and not dilated. There was good contractility without regional wall motion abnormalities.... I then measured the left ventricular end diastolic and end systolic areas with electronic calipers and calculated the ejection fraction by Simpson's Method. The average left ventricular end diastolic volume in the apical four chamber view was

8. Claimant also argues that Dr. Bier's opinion should not be considered because he did not provide the disclosures required by Rule 26(a)(2) and did not meet the pleading requirement of Rule 9(b). As we have previously stated, Rule 26(a)(2) disclosures are not required under the Audit Rules. See PTO No. 6996 at 7 n.10 (Feb. 26, 2007). There similarly is no requirement under the Audit Rules that the opinion of an auditing cardiologist, which is not a pleading, meet the requirements of Rule 9(b).

calculated to be 102.6 ml. The average left ventricular end systolic volume in the apical four chamber view was calculated to be 40.5 ml. The average end diastolic left ventricular volume in the apical two chamber view was calculated to be 130.5 ml. The average end systolic volume in the apical two chamber view was calculated to be 47.0 ml. Therefore, the average ejection fraction calculated via Simpson's Method was 62%.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not challenge the findings of the Technical Advisor. Specifically, Dr. Vigilante reviewed the claimant's April 22, 2003 echocardiogram and concluded that Ms. Moon's ejection fraction was 62% calculated using Simpson's Method. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

We also disagree with claimant that the letter from Dr. Szwajkun establishes a reasonable medical basis for his representation that Ms. Moon had a reduced ejection fraction. Dr. Bier and Dr. Vigilante reviewed claimant's echocardiogram and determined that Ms. Moon's ejection fraction was greater than 60%. Specifically, Dr. Bier calculated her ejection fraction to be 63% and Dr. Vigilante calculated her ejection fraction to be 62%. Dr. Vigilante also noted that it would be unreasonable for an echocardiographer to conclude that Ms. Moon's ejection fraction was in the range of 50% to 60% even taking into consideration inter-reader variability. In addition, Dr. Bier

explained that the "tracing recorded on the tape for end diastole is about 1-2 frames after the true end-diastole as judged by the ECG tracing." Dr. Szwajkun failed to address both the specific measurements and Dr. Bier's assignment of error in the measurement.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had a reduced ejection fraction. Therefore, we will affirm the Trust's denial of Ms. Moon's claim for Matrix Benefits and the related derivative claims submitted by her children.